



**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: A8461

James E. GALEN

Appln. No.: 09/993,292

Group Art Unit: 1645

Confirmation No.: 5386

Examiner: Duffy, P.

Filed: November 23, 2001

For: USE OF ClyA HEMOLYSIN FOR EXCRETION OF PROTEINS

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

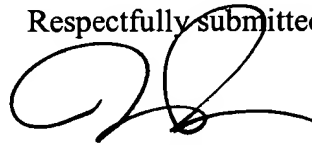
One copy of each of the listed documents is submitted herewith.

The present Information Disclosure Statement is being filed (without a Statement Under 37 C.F.R. § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore a check for the fee of \$180.00 under 37 C.F.R. §1.17(p) is attached.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



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Drew Hissong  
Registration No. 44,765

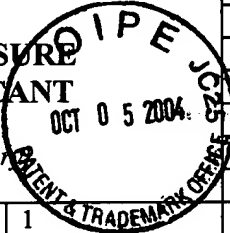
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**23373**

CUSTOMER NUMBER

Date: October 5, 2004

Substitute for Form 1449 A & B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	09/993,292
				Confirmation Number	5386
				Filing Date	November 23, 2001
				First Named Inventor	James E. GALEN
				Art Unit	1645
				Examiner Name	Duffy, P.
Sheet 1 of 1				Attorney Docket Number	A8461

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Atkins et al, <i>J. Biol. Chem.</i> , <u>275</u> :41150-41155 (2000)	
		Bramucci et al, <i>Appl. Environ. Microbiol.</i> , <u>62</u> :3948-3953 (1996)	
		Corchero et al, <i>Biotechnol. Bioeng.</i> , <u>58</u> :625-632 (1998)	
		Cserjan-Puschmann et al, <i>Appl. Microbiol. Biotechnol.</i> , <u>53</u> :43-50 (1999)	
		del Castillo et al, <i>Mol. Microbiol.</i> , <u>25</u> :107-115 (1997)	
		Galen et al, <i>Trends in Microbiology</i> , <u>9</u> :372-376 (2001)	
		Hess et al, <i>Proc. Natl. Acad. Sci., USA</i> , <u>93</u> :1458-1463 (1996)	
		Ludwig et al, <i>Mol. Microbiol.</i> , <u>31</u> :557-567 (1999)	
		Wallace et al, <i>Cell</i> , <u>100</u> :265-276 (2000)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.